

## **Surveillance for Vaccine Adverse Events: Vaccine Adverse Event Reporting System (VAERS)**

### **Background**

The Vaccine Adverse Event Reporting System (VAERS) is a national program which collects information about potential adverse events associated with vaccinations for the purpose of monitoring the safety of vaccines which are used in the United States. The National Childhood Vaccine Injury Act (NCVIA) of 1986 mandated reporting of certain adverse events. The US Department of Health and Human Services created VAERS in 1990. The national database of VAERS reports provides a means for analyzing the occurrence and nature of possible adverse events related to immunizations. The VAERS system is operated jointly by the Centers for Disease Control and Prevention (CDC) and the Food and Drug Administration (FDA). These agencies monitor VAERS reports to determine if any vaccine or vaccine lot has a higher than expected rate of events and the types of events reported for each vaccine. They watch for associations between vaccines and rare events that may not have been identified during clinical trials.

### **Content of VAERS Reports**

Any clinically significant adverse event occurring after administration of any vaccine licensed in the US should be reported, even if it is not certain that the event was caused by the vaccine. Required reports include any event listed in NCVIA reportable event table and any event listed in the package insert as a contraindication to subsequent doses. The Reportable Event Table (RET) is subject to change; the latest version of the RET is available through the VAERS Internet website: [www.vaers.hhs.gov/pdf/ReportableEventsTable.pdf](http://www.vaers.hhs.gov/pdf/ReportableEventsTable.pdf). A copy of the table can also be obtained by calling VAERS at (800) 822-7967.

**Note:** Reports of **vaccine administration errors** should be directed to the **Institute for Safe Medication Practices (ISMP)** and can be reported on-line securely and confidentially via the ISMP website at [www.ismp.org](http://www.ismp.org) by clicking on the “Report Errors” link. Examples of vaccine administration errors include wrong dosage, incorrect route, wrong age, wrong vaccine formulation, administration despite a contraindication, etc.

A VAERS report is not documentation that a vaccine caused the event. The Reportable Event Table specifically outlines the reportable post-vaccination events and the time frames of events that are reportable by law.

Submitting a VAERS report does NOT constitute reporting to or filing a claim with the **National Vaccine Injury Compensation Program**. See [National Vaccine Injury Compensation Program section](#) below for information on contacting the NVICP.

### **Completing a VAERS report**

Anyone may submit VAERS report. Most VAERS reports are submitted by health care providers, vaccine manufacturers, and vaccine recipients (or their parents/guardians). Patients or

parents/guardians are encouraged to seek the help of their health care professional in filling out the VAERS form.

Reports of possible vaccine adverse events should be made by completing a VAERS form (forms are available for downloading at [www.vaers.hhs.gov/pdf/vaers\\_form.pdf](http://www.vaers.hhs.gov/pdf/vaers_form.pdf)). All information indicated on the form should be obtained and recorded. Vaccine information (type, manufacturer, lot numbers, site of injection) are especially important. Follow the instructions on the reverse side of the VAERS form.

Alternatively, VAERS reports can be completed and submitted electronically via the internet; go to [www.vaers.hhs.gov](http://www.vaers.hhs.gov) and click on the **VAERS Web Submission** link, then follow the instructions.

## Submission of VAERS report

Currently, paper VAERS reports are addressed to one of two different recipients depending on the sector type of the provider who gave the vaccine in question:

1. Reports involving immunizations administered by **private sector** providers (physician offices, hospitals, non-public health clinics, etc):

- Use the VAERS form with the “postage paid” permit
- Should be submitted directly to the national VAERS program office (VAERS PO Box 1100, Rockville MD 20849-1100)

**Note:** it is also acceptable to submit a VAERS report on-line (go to [www.vaers.hhs.gov](http://www.vaers.hhs.gov), then click on the **VAERS Web Submission** link). It is advisable to print and retain the report (with the system-generated “e-VAERS” number) for possible future reference.

2. Reports involving immunizations administered in the **public sector** (health department clinics and programs):

- Paper reports should be submitted to:  
MDCH Division of Communicable Disease and Immunization  
Attention: VAERS Coordinator  
PO Box 30195  
Lansing, MI 48909
- MDCH will review the report and forward report to national VAERS program office

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to [www.vaers.hhs.gov](http://www.vaers.hhs.gov), then click on the **VAERS Web Submission** link). It is advisable to print and retain the report (with the system-generated “e-VAERS” number) for possible future reference.

## **National Vaccine Injury Compensation Program**

The National childhood Vaccine Injury Act of 1986 established the National Vaccine Injury Compensation Program. The program is a Federal “no fault” system designed to compensate those individuals, or families of individuals, who have been injured by childhood vaccines, whether administered in the private or public sector.

Additional information (information packet detailing filing a claim, criteria for eligibility, and required documentation on the program) can be obtained by contacting the program directly:

Parklawn Building, Room 11C-26  
5600 Fishers Lane  
Rockville, Maryland 20857  
1-800-338-2382  
Internet/Web site: <http://www.hrsa.gov/vaccinecompensation/default.htm>

For information on the rules of the U.S. Court of Federal Claims, including requirements for filing a petition, contact:

Clerk  
US Court of Federal Claims,  
717 Madison Place N.W.  
Washington, D.C. 20005  
202) 357-6400

